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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,430	02/13/2006	Markus Hecker	DEBE:052US/10501403	9671

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
08/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/526,430	**Applicant(s)** HECKER ET AL.	
	Examiner David Montanari	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *11-19*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Peter Paras, Jr./
Supervisory Patent Examiner, Art Unit 1632

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments are not considered persuasive.

Claims 11-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chouini-Lalanne et al. (1998, Biochemical Pharmacology, Vol. 55, pgs. 441-446) and Ajmone-Cat et al. (2001, J. of Neuroscience Res., Vol. 66, pgs. 715-722) for reasons of record in the office actions mailed on 10/17/2007 and 4/16/2008.

Response to Arguments

Applicants argue in their response that the claim limitation of "pharmaceutical formulation" cannot be ignored and must be considered on its merits. Applicants argue that In re Lerner teaches that an otherwise unpatentable compound would not be rendered patentable by addition of a carrier or diluent, how if the use of the carrier would not be obvious, the resulting composition would then be patentable. Applicants argue that they are their own lexicographer, and that the Examiner is compelled to interpret the claims therein in light of the Applicant's specification. Applicants cite in their arguments pg. 7 lines 16-24 of the specification which provides a definition of "pharmaceutical formulation". Applicants continue to argue the definition of "pharmaceutical formulation" is further defined and clarified by www.answers.com. Applicants continue that just because a composition of matter may be used in ways not intende, it does not mean that the Examiner is free to ignore limitations that relate to other uses. Applicants continue that this rejection is one of obviousness, not inherent anticipation, and thus the question is why one would modify the teachings of Chouini-Lalanne, which disclose the use of DNA as a target for possible phototoxic actions of NSAID's, to prepare a formulation suitable not just for the in vitro test that was described, but for in vivo administration of a DNA-NSAID combinatin. Applicants continue that Ajmone-Cat cannot provide any such modivation given that it merely discusses NSAID's and thus says nothing about adding DNA to a pharmaceutical formulation of an NSAID. Applicants continue that is is black letter law that the Examiner must take into consideration the pharmaceutical formulation limitation of the present claims, and when considered, it is clear that the cited art fails to suggest such an invention.

Regarding the pH range limitations of the pending claims, Applicants argue that even "optimization" requires some motivation and that an examintation of Chouini-Lane (pH 7.4) the Applicants question what motivation is there to drop the pH from the stated 7.4 to 6.2-7.0? Applicants continue that there is no motivation provided and that hand-waiving optimization is insufficient, because you can only optimize that for which there is motivation to cause change. Applicants continue that in a vain attempt the Examiner argues that there is still sufficient motivation from Applicants intended in vivo use to drop the pH from Chouini-Lalanne's 7.4 to the "art accepted physiological pH of 7.0".

Applicants finish with the argument that the evidence or record shows a surprising result stemming from the lowering of the pH from 7.4 to 7.0, namely, an increase in DNA uptake by 50%. These arguments are not persuaive.

Addressing the pharmaceutical formulation limitation of the claimed invention, Applicants have directed attention to the definition of pharmaceutical formulation in the specification which recites:

"The term "formulation" or "pharmaceutical formulation" as used in the present document means the pharmaceutical form of preparation, for example, for a drug or an inoculation medium, which his administered in vivo to a human or an animal, or in vitro or ex vivo to organs, tissues or cells, consisting of one or more active ingredients and auxilliary formulation agents. Active ingredients according to the present invention are nucleic acids". (pg. 7 lines 16-24)

Given this definition provided by the specification concerning how pharmaceutical formulation should be interpreted, it appears that Chouini-Lalanne would still teach the invention. Claim 11 requires 1) a nucleic acid and 2) an NSAID at a pH range, if the active ingredient is nucleic acids, then it is entirely within reason that the NSAID is the auxillary agent, and thus the teachings of Chouini-Lalanne would also encompass a pharmaceutical composition. Thus for these reasons the claim limitations are met regarding a pharmaceutical formulation. The specification does not teach that the NSAID's used in the claimed formulation will be the active ingredient, but rather will provide increased DNA uptake and thus fill the auxillary role as defined in the specification cited above.

Regarding Applicants arguments concerning the pH range limitation in the pending claims, Applicants have failed to address or argue a part of the 35 USC 103(a) rejection mailed on 10/17/2007 (see pg. 4 starting with parag. 2 and finishing on pg. 5) which teaches that it is well settled that routine optimization is not patentable, In re Aller, Lacey and Hall, 105 USPQ (CCPA 1955). The instant rejection stated that "However, even though an applicants modifications results in great improvement and utility over the prior art, it may still not be patentable if the modifications was within the capabilities of one skilled in the art" In re Sola. In neither of Applicants responses filed on 1/15/2008 and 6/12/2008 have they addressed the court settled issue of routine optimization and its effect on patentability. Given these teachings in the pending art rejection, the claim limitation of the pH range of 6.2-7.0 has been addressed and the art of record would lead the ordinary artisan to find the claimed invention obvious. Thus for the reasons above and of record the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU 1632